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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,308	02/01/2002	David L. Rimm	YUA-001.01	2553

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SAF.

## Office Action Summary

### Application No.

10/062,308

### Applicant(s)

RIMM ET AL.

### Examiner

Channing S Mahatan

### Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### *APPLICANTS' ARGUMENTS*

Applicants' arguments, filed 04 March 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-32 and 39.

This application contains claim 33-38 drawn to an invention non-elected with traverse in the 'Telephone Election' on 06 November 2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

### *DEFECTIVE OATH OR DECLARATION*

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by application number and filing date is required. See M.P.E.P. § 602.01 and 602.02.

The oath or declaration is defective because the filing date of United States Provisional application 60/285,155 to which Applicants claim of benefit under Title 35 U.S.C. 119(e) is incorrect. The filing date of United States Provisional application 60/285,155 is April 20, 2001, not April 19, 2001.

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Additionally, Applicants' are requested to correct the filing date within the specification corresponding to U.S. Provisional Application 60/285,155.

### **Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

Claims 1-13, 30-32, and 39 are rejected under 35 U.S.C. § 102(e) as being anticipated by Dunlay et al. (U.S. Patent Number 6,727,071).

Dunlay et al. discloses systems, methods, and screens for an optical system analysis of cells to rapidly determine the distribution, environment, or activity of fluorescently labeled reporter molecules in cells by combining many cell screening formats with fluorescence-based molecular reagents and computer-based feature extraction, data analysis, and automation thereby significantly improve target validation and candidate optimization (Abstract; and Column 5, lines 28-40). The disclosed invention is indicated to include an apparatus and a computerized method for processing, displaying and storing of obtained information (Abstract) and the cell images are

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acquired utilizing a microscope and digital camera (i.e. pixel image) (Columns 9-10). The disclosed cell screening method provides for detecting three-dimensional probes through the acquisition of images from multiple focal planes to account for probes stacked on top of each other in the Z-direction, wherein cells are three-dimensional in nature and when examined at high magnification under a microscope one probe maybe in-focus while another may be completely out of focus (Column 17, lines 25-45). With regard to the claim limitation “reducing representation of out-of-focus elements”, Dunlay et al. indicates the disclosed invention allows for the selection of an auto-focusing procedure or a user interactive focusing procedure (Column 14, lines 61-66), thus, bringing an image into focus would “reduce representation of out-of-focus elements” (claim 7). One example provided by the inventors is for the screening of compounds that induce or inhibit nuclear translocation of a DNA transcription factor (Example 1; Columns 22-24). The distribution of a transcription factor is determined by labeling the nucleus of a cell with a DNA specific fluorophore (Hoechst 3323) and the transcription factor in the cytoplasm with a specific fluorescent antibody (Column 23, lines 5-8). A nuclear mask (i.e. first image) is created by acquiring an image of the nucleus based upon optional thresholds and is subsequently used to extract transcription factor distributions (Column 23, lines 8-21). The nuclear mask is then superimposed on/compared to the labeled images (i.e. second image) of an unstimulated cell or a stimulated cell to determine the localization of the transcription factor to the nucleus (Figures 10A-10-J). Differences in the average fluorescence intensity in the nucleus sampling region and cytoplasmic sampling region can be calculated, plotted, and displayed (i.e. binned; Column 24, lines 10-31; and Figure 18). The inventors provide other examples of translocation determination between different cellular compartments; plasma membrane and cytoplasm

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(Columns 33) and endoplasmic reticulum and golgi (Column 35). Additionally, Dunlay et al. discloses various methodologies for labeling cellular compartments applicable to the disclosed invention, such methodologies include whole cell labeling (column 39, lines 28-56), plasma membrane labeling (columns 39-40, lines 57-67 and 1-45, respectively); endosome fluorescent labeling (column 40, lines 46-64), lysosome labeling (columns 40-41, lines 65-67 and 1-22, respectively), cytoplasmic fluorescence labeling (columns 41-42, lines 23-67 and 1-16), nuclear labeling (column 42, lines 17-45), mitochondria labeling (column 42-43, lines 46-67 and 1-9, respectively), endoplasmic reticulum labeling (column 43, lines 10-31), and golgi labeling (column 43, lines 32-52). Thus, Dunlay et al. anticipate the claimed invention.

### **Claims Rejected Under 35 U.S.C. § 103**

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-32 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dunlay et al.

Dunlay et al. is herein applied from above the 35 U.S.C. § 102(e) Rejection. However, Dunlay et al. does not specifically provide an example of labeling cell compartments with additional stains (i.e. third and fourth). With respect to claims 14-29 regarding these additional stains Dunlay et al. describes a various methodologies for labeling cellular compartments (Columns 39-43) and states:

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“While many of the examples presented involve the measurement of single cellular processes, this is again intended for purposes of illustration only. Multiple parameter high-content screens can be produced by combining several single parameter screens into a multiparameter high-content screen or by adding cellular parameters to any existing high-content screen (Column 43, lines 53-59).

Thus, it would have been obvious to one of skill in the art to perform multiple staining, multiple image acquisition, and multiple image analysis for multiple parameter high-content screens, since Dunlay et al. indicates that the provided examples were intended for illustration only and one in the art would “recognize a wide variety of distinct screens that can be developed based on the disclosure provided” (Column 43, lines 63-65).

**No Claims Are Allowed.**

*ACTION IS FINAL, NECESSITATED BY AMENDMENT*

Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
*6/10/04*  
*411631*